

## REMARKS

Reconsideration in light of the following remarks is respectfully requested. Claims 1-23 are pending.

### Claim Rejections – 35 U.S.C. § 103(a)

#### Gallo

##### A. The Examiner's Rejection

Claims 1-11, 14-18, and 20-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gallo et al. (Genetica (1997) 110: 1-12).

##### B. The Claimed Invention

Claim 1 is directed to a method of assigning an individual to a population of origin. The claim includes steps (a)-(g). Notably, step (b) requires “determining a *population prior genotype probability* for an individual ...” Step (e) requires “combining the *population prior genotype probability* from step (b) ...” Step (f) requires “identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ...” Finally, step (g) requires “assigning the individual to the most likely population of origin ...”

##### C. Cited Reference

The Examiner has stated that Gallo et al teach that you can determine the frequency of the suspect's profile against the relevant population databases. The Examiner has also stated that “Gallo does not teach the method steps as specifically outlined in the claimed invention...”

The Examiner has made further assertions about specific law enforcement practices. The Examiner has provided no support for these assertions. Applicants are unaware of the source of such assertions and therefore can not evaluate the relevance to the obviousness rejection.

Applicants respectfully traverse this assertion and request that the Examiner provide references that discuss such law enforcement practices so that the applicants can better understand the Examiner's rejection. MPEP § 2144.03 "If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position."

D. Reference Distinguished

35 USC 103(a) states "a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The *prima facie* case must satisfy three requirements: 1) the references must teach or suggest all the claim limitations; 2) the prior art combined with general knowledge must include a suggestion or incentive to modify or combine the references; and 3) the modification or combination must have a reasonable chance of success.

*No prima facie case:*

The Examiner fails to establish a *prima facie* case for obviousness. Specifically, 1) none of the cited references teach or suggest all of the claim limitations and 2) the prior art combined with general knowledge fails to include a suggestion or incentive to modify the references.

First, the reference fails to teach all limitations of the claimed invention. Specifically, the claims require "determining a ***population prior genotype probability*** for an individual ..." The Examiner has stated that law enforcement personnel carry out this step by "selecting only individuals who they believe may have committed the crime by using knowledge of the individual, such as the whereabouts of the individuals at the time of the crime, or a description of the individual, such as, height, hair color, skin color, etc." Without an actual reference, it is difficult to evaluate this statement; however, there appears to be no actual calculation of any prior genotype probability for an individual based upon such characteristics as height, hair color,

skin color, etc. Furthermore, the whereabouts of the suspect does not appear to be relevant to the prior genotype probability, unless there is some genetic propensity for an individual to be at a particular location, e.g., a crime scene. In addition, Gallo et al do not teach determining a population prior genotype probability for an individual.

Furthermore, the references fail to teach combining the *population prior genotype probability* from step (b) and the population genotype from step (d) to obtain a population posterior genotype probability for the individual and said each candidate population. The Examiner has asserted that “law enforcement will determine whether a match between the suspect’s DNA profile and that found at the crime scene.” This does not include combining prior probability information with new probability information as is required by this step to generate a posterior probability. As stated by the Examiner, law enforcement personnel use the new data from the DNA profile without reference to the prior information. Furthermore, it is unclear from the Examiner’s statements whether a probability is being determined at all. Thus, law enforcement personnel may not perform step (d) either. Again, Gallo et al do not teach combining a population prior genotype probability with the population genotype, because Gallo et al do not teach determination of a population prior genotype probability.

Finally, since neither the Examiner’s discussion of law enforcement practice nor Gallo et al include steps (b) or (e), neither could teach step (f) because step (f) requires “identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ...” Since neither teaches generating a population posterior genotype probability.

Thus, the Examiner has not established a *prima facie* case, because the references cited fail to teach all claim limitations. Specifically, the references fail to teach steps (b), (e), and (f).

Second, the Examiner has identified no motivation or suggestion in either discussing law enforcement practice or in Gallo et al to make any modifications or combine other references. The MPEP is clear that a suggestion or motivation is not just any comment that modification of a reference or combination of references can be done. See MPEP 2143.01, “The prior art must

suggest the *desirability* of the claimed invention.” The Examiner has merely stated that, “it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime.” The Examiner, however, has not cited to any motivation or suggestion that it would be desirable to add the missing claimed steps. Neither Gallo et al. nor the Examiner’s discussion of law enforcement practice mention the missing claimed steps. Nor does a general desire to achieve the benefit of a higher predictability supply the necessary motivation. A general desire such as this does not lead specifically to the claimed invention. It merely motivates one of skill in the art to explore all the myriad possible ways to improve the accuracy of positively identifying the perpetrators of crimes.

Thus, even if Gallo et al and the Examiner’s discussion of law enforcement practice supplied all claim elements, there is no motivation to combine them nor is there motivation to modify either to achieve the claimed invention.

#### Triggs

##### A. The Examiner’s Rejection

Claims 1-11, 14-18, and 20-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Triggs (Science and Justice (2000) 40(1): 33-38).

##### B. The Claimed Invention

Claim 1 is directed to a method of assigning an individual to a population of origin. The claim includes steps (a)-(g). Notably, step (b) requires “determining a *population prior genotype probability* for an individual ...” Step (e) requires “combining the *population prior genotype probability* from step (b) ...” Step (f) requires “identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior*

*genotype probability ...*” Finally, step (g) requires “assigning the individual to the most likely population of origin ...”

C. Cited Reference

The Examiner has stated that Triggs teaches “methods for assigning individuals from a population in mixed race populations, and more specifically outlines several different case scenarios for assignment based on the steps outlined above.” The Examiner has also stated that “Triggs does not teach the method steps as specifically outlined in the claimed invention...”

As discussed above, the Examiner has made further assertions about specific law enforcement practices. The Examiner has provided no support for these assertions. Applicants are unaware of the source of such assertions and therefore can not evaluate the relevance to the obviousness rejection. Applicants respectfully traverse this assertion and request that the Examiner provide references that discuss such law enforcement practices so that the applicants can better understand the Examiner’s rejection. MPEP § 2144.03 “If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position.”

D. Reference Distinguished

35 USC 103(a) states “a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” The *prima facie* case must satisfy three requirements: 1) the references must teach or suggest all the claim limitations; 2) the prior art combined with general knowledge must include a suggestion or incentive to modify or combine the references; and 3) the modification or combination must have a reasonable chance of success.

*No prima facie case:*

The Examiner fails to establish a prima facie case for obviousness. Specifically, 1) none of the cited references teach or suggest all of the claim limitations and 2) the prior art combined with general knowledge fails to include a suggestion or incentive to modify the references.

First, the reference fails to teach all limitations of the claimed invention. Specifically, the claims require “determining a *population prior genotype probability* for an individual ...” The Examiner has stated that law enforcement personnel carry out this step by “selecting only individuals who they believe may have committed the crime by using knowledge of the individual, such as the whereabouts of the individuals at the time of the crime, or a description of the individual, such as, height, hair color, skin color, etc.” Without an actual reference, it is difficult to evaluate this statement; however, there appears to be no actual calculation of any prior genotype probability for an individual based upon such characteristics as height, hair color, skin color, etc. Furthermore, the whereabouts of the suspect does not appear to be relevant to the prior genotype probability, unless there is some genetic propensity for an individual to be at a particular location, e.g., a crime scene. In addition, Triggs does not teach determining a population prior genotype probability for an individual.

Furthermore, the references fail to teach combining the *population prior genotype probability* from step (b) and the population genotype from step (d) to obtain a population posterior genotype probability for the individual and said each candidate population. The Examiner has asserted that “law enforcement will determine whether a match between the suspect’s DNA profile and that found at the crime scene.” This does not include combining prior probability information with new probability information as is required by this step to generate a posterior probability. As stated by the Examiner, law enforcement personnel use the new data from the DNA profile without reference to the prior information. Furthermore, it is unclear from the Examiner’s statements whether a probability is being determined at all. Thus, law enforcement personnel may not perform step (d) either. Again, Triggs does not teach combining a population prior genotype probability with the population genotype, because Triggs does not teach determination of a population prior genotype probability.

Finally, since neither the Examiner's discussion of law enforcement practice nor Triggs include steps (b) or (e), neither could teach step (f) because step (f) requires "identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ..." Since neither teaches generating a population posterior genotype probability.

Thus, the Examiner has not established a *prima facie* case, because the references cited fail to teach all claim limitations. Specifically, the references fail to teach steps (b), (e), and (f).

Second, the Examiner has identified no motivation or suggestion in either discussing law enforcement practice or in Triggs to make any modifications or combine other references. The MPEP is clear that a suggestion or motivation is not just any comment that modification of a reference or combination of references can be done. See MPEP 2143.01, "The prior art must suggest the *desirability* of the claimed invention." The Examiner has merely stated that, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime." The Examiner, however, has not cited to any motivation or suggestion that it would be desirable to add the missing claimed steps. Neither Triggs nor the Examiner's discussion of law enforcement practice mention the missing claimed steps. Nor does a general desire to achieve the benefit of a higher predictability supply the necessary motivation. A general desire such as this does not lead specifically to the claimed invention. It merely motivates one of skill in the art to explore all the myriad possible ways to improve the accuracy of positively identifying the perpetrators of crimes.

Thus, even if Triggs and the Examiner's discussion of law enforcement practice supplied all claim elements, there is no motivation to combine them nor is there motivation to modify either to achieve the claimed invention.

## Ron

### A. The Examiner's Rejection

Claims 1-12, 14-20 and 22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ron et al (J of Dairy Science (1996) 79(4): 676-681).

### B. The Claimed Invention

Claim 1 is directed to a method of assigning an individual to a population of origin. The claim includes steps (a)-(g). Notably, step (b) requires “determining a *population prior genotype probability* for an individual ...” Step (e) requires “combining the *population prior genotype probability* from step (b) ...” Step (f) requires “identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ...” Finally, step (g) requires “assigning the individual to the most likely population of origin ...”

### C. Cited Reference

The Examiner has stated that Ron et al teach the DNA analysis of one hundred seventy-three cows, the progeny of four sires, which were sampled from 14 herds. The Examiner has asserted that this encompasses claimed steps (a) and (b). However, a review of the page 677 cited by the Examiner reveals no mention of determination of a population prior genotype probability for an individual and each said candidate population using knowledge concerning the individual which is available *prior* to genotyping the individual. The Examiner has further stated that the probabilities from step (b) and (d) were combined to determine the most likely population of origin of the cows. A review of pages 678 and 679 cited by the Examiner reveals no mention of combining a population prior genotype probability with a population genotype probability to obtain a population posterior genotype probability. The Examiner also further stated that “Ron does not teach the method steps as specifically outlined in the claimed invention...”



#### D. Reference Distinguished

35 USC 103(a) states “a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” The *prima facie* case must satisfy three requirements: 1) the references must teach or suggest all the claim limitations; 2) the prior art combined with general knowledge must include a suggestion or incentive to modify or combine the references; and 3) the modification or combination must have a reasonable chance of success.

##### *No prima facie case:*

The Examiner fails to establish a *prima facie* case for obviousness. Specifically, 1) none of the cited references teach or suggest all of the claim limitations and 2) the prior art combined with general knowledge fails to include a suggestion or incentive to modify the references.

First, the reference fails to teach all limitations of the claimed invention. Specifically, the claims require “determining a ***population prior genotype probability*** for an individual ...” As discussed above, Ron et al do not teach determining a population prior genotype probability for an individual.

Furthermore, the references fail to teach combining the ***population prior genotype probability*** from step (b) and the population genotype from step (d) to obtain a population posterior genotype probability for the individual and said each candidate population. Again as discussed above, Ron et al do not teach combining a population prior genotype probability with the population genotype, because Ron et al do not teach determination of a population prior genotype probability.

Additionally, since Ron et al fail to teach steps (b) or (e), Ron et al could not teach step (f) because step (f) requires “identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ...”

Finally, Ron et al teach the exclusion of paternity. This does not encompass steps (f) and (g). Ron et al merely describe a method of excluding a sire as a parent of an individual without reference to information obtained prior to genotyping the individual. Ron et al do not after excluding a particular sire as a parent continue to evaluate other sires to identify the most likely population of origin for that individual. Thus again, Ron et al fail to teach step (f) and therefore step (g).

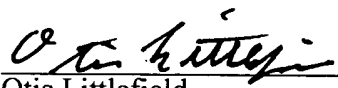
Thus, the Examiner has not established a *prima facie* case, because the references cited fail to teach all claim limitations. Specifically, the reference fails to teach steps (b), (e), (f), and (g).

Second, the Examiner has identified no motivation or suggestion in Ron et al to make any modifications or combine other references. The MPEP is clear that a suggestion or motivation is not just any comment that modification of a reference or combination of references can be done. See MPEP 2143.01, “The prior art must suggest the *desirability* of the claimed invention.” The Examiner has merely stated that, “it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime.” The Examiner, however, has not cited to any motivation or suggestion that it would be desirable to add the missing claimed steps. Ron et al do not mention the missing claimed steps or suggest adding them. Nor does a general desire to achieve the benefit of a higher predictability supply the necessary motivation. A general desire such as this does not lead specifically to the claimed invention. It merely motivates one of skill in the art to explore all the myriad possible ways to improve the accuracy of positively identifying the perpetrators of crimes.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 529642000800.

Respectfully submitted,

Dated: April 24, 2003

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## APPENDIX OF THE PENDING CLAIMS

1. (Previously Amended) A method of assigning an individual to a population of origin, which comprises:

(a) identifying a set of candidate populations of origin, wherein each candidate population is characterized by genotype frequencies and allele frequencies at one or more marker loci;

(b) determining a population prior genotype probability for an individual and said each candidate population using knowledge concerning the individual which is available prior to genotyping the individual;

(c) genotyping the individual to identify alleles at the one or more marker loci in step (a) to thereby identify the individual's genotype;

(d) sequentially determining a population genotype probability for the individual and said each candidate population based on the genotype of the individual under a null hypothesis that the individual arose from said each candidate population;

(e) combining the population prior genotype probability from step (b) and the population genotype probability from step (d) to obtain a population posterior genotype probability for the individual and said each candidate population;

(f) identifying a most likely population of origin, wherein the most likely population of origin has the largest population posterior genotype probability among the set of candidate populations; and

(g) assigning the individual to the most likely population of origin identified in step (f).

2. (Previously Amended) The method of claim 1, wherein the individual is only assigned to the most likely population of origin if the population posterior genotype probability for the most likely population of origin exceeds a threshold value.

3. (Previously Amended) The method of claim 1, which further comprises:

(a) computing an additional probability with which genotypes rarer than the individual's genotype occur in the most likely population of origin; and

(b) if the additional probability in step (a) is above a threshold value, assigning the individual to the most likely population of origin, or if the additional probability in step (a) is not above the threshold value, assigning the individual to a novel population that is not represented among the set of candidate populations of origin.

4. (Original) The method of claim 2, wherein the threshold value is determined empirically.

5. (Previously Amended) The method of claim 4, wherein the threshold value is determined using population posterior genotype probabilities of a sample of individuals from said each candidate population who are independent of individuals used to characterize said each candidate population.

6. (Previously Amended) The method of claim 4, wherein the threshold value is varied to determine the percentage of a sample of individuals who a) cannot be classified, b) are correctly classified, and c) are incorrectly classified.

7. (Original) The method of claim 3, wherein the threshold value is determined empirically.

8. (Previously Amended) The method of claim 7, wherein the threshold value is determined using population posterior genotype probabilities of a sample of individuals from said each candidate population who are independent of individuals used to characterize said each candidate population.

9. (Previously Amended) The method of claim 7, wherein the threshold value is increased to reduce the percentage of a sample of individuals who are incorrectly classified to one of the candidate populations of origin.

10. (Original) The method of claim 1, wherein the population prior genotype probability is based on one or more morphological features of the individual.

11. (Previously Amended) The method of claim 10, wherein the one or more morphological features allow the exclusion of one or more of the candidate populations of origin.

12. (Previously Amended) The method of claim 11, wherein the one or more morphological features are selected from the group consisting of coat color, presence or absence of horns, presence or absence of a shoulder hump, and presence or absence of a long, downswept ear.

13. (Original) The method of claim 12, wherein the coat color is black or nonblack.

14. (Previously Amended) The method of claim 1, wherein the population prior genotype probability for the individual and said each candidate population is set to equal a proportion of total population size in said each candidate population.

15. (Previously Amended) The method of claim 1, wherein the population prior genotype probability for the individual and said each candidate population is uniform.

16. (Previously Amended) The method of claim 1, wherein marker locus genotypes for said each candidate population are in Hardy-Weinberg Equilibrium and Gametic Phase Equilibrium.

17. (Previously Amended) The method of claim 1, wherein marker locus genotypes for said each candidate population are not in Hardy-Weinberg Equilibrium or Gametic Phase Equilibrium.

18. (Original) The method of claim 1, wherein the individual is an animal.

19. (Original) The method of claim 18, wherein the animal is a cow, a heifer, a steer, a bull, a bullock, a pig, a horse, a fish, a chicken, a duck, a lamb, a shrimp, an oyster, a mussel, or a shellfish.

20. (Previously Amended) The method of claim 1, wherein the alleles at the one or more marker loci are selected based on additive effects of the alleles on a desirable trait such that said assigning is based on the desirable trait.

21. (Original) The method of claim 20, wherein the desirable trait is selected from the group consisting of one or more of animal growth, quality grade, yield grade, marbling, rib-eye muscle area, dressing percentage, meat tenderness, meat flavor, meat palatability, fatness, fat color, unsaturated fatty acid content of fat, reproductive efficiency, prolificacy, disease resistance, feed conversion efficiency, drought tolerance, and heat tolerance.

22. (Previously Amended) The method of claim 1, wherein the alleles at the one or more marker loci are selected based on additive effects of the alleles on an undesirable trait such that said assigning is based on the undesirable trait.

23. (Original) The method of claim 22, wherein the undesirable trait is toughness of meat.